Congress of the United States
House of Representatives
Washington, D.C. 20515

Dear Colleague:

As you may know, Energy and Commerce Committee investigators recently revealed how flaws in Medicare's drug-reimbursement system are being used to dramatically inflate drug payments.

The mechanisms for this scheme are complicated. But the net effect is that taxpayers are bilked out of billions of dollars, and Medicare beneficiaries – especially those undergoing chemotherapy to treat cancer or using respiratory drugs to treat conditions like emphysema -- lose hundreds of millions of dollars each year out-of-pocket and are put at risk of receiving substandard care.

Attached you will find a Chicago Tribune article that details a record settlement by one company, TAP Pharmaceutical Products Inc. TAP recently settled a case involving Medicare prices for its prostate cancer drug, Lupron, which resulted in the payment of $875 million to the government, the largest health care fraud related settlement in U.S. history. In addition, several current and former TAP employees are under indictment. One other manufacturer has settled a similar case, and several other manufacturers are reported to be the subjects of similar investigations. We urge you to read this article, but also to recognize that the problem goes well beyond the practices of individual drug manufacturers.

No matter how vigorous, investigations and prosecutions will not resolve this issue. Despite the $875 million settlement and the indictments, Medicare continues to base its reimbursement for Lupron, and other Medicare-covered drugs, upon inflated Average Wholesale Prices (AWPs) reported by drug manufacturers. This reliance upon easily manipulated AWPs was identified in the Committee's recent hearing as the principal reason why Medicare conservatively loses hundreds of millions of dollars every year due to inflated drug reimbursements. The TAP case simply underscores how important it is for Congress to fix the current Medicare drug reimbursement system.

If you or your staff should have any questions or require any additional information about the hearing, or this topic generally, please contact Energy and Commerce Committee Majority counsel Chuck Clapton at 226-2424 and Minority counsel Edith Holleman at 226-3400.

Sincerely,

Cancer drug probe nets $875 million settlement

By Bruce Japsen, Andrew Zajac and Laurie Cohen, Tribune staff reporters
Published October 4, 2001

BOSTON -- In the largest health-care fraud settlement in U.S. history, drugmaker TAP Pharmaceutical Products Inc. of Lake Forest Wednesday agreed to pay $875 million and plead guilty to a criminal charge of conspiring with doctors to overbill government insurers for its prostate cancer drug Lupron.

In addition, six current and former TAP managers and a Massachusetts physician were charged with conspiring to pay kickbacks and bribes to doctors and other customers at the expense of government Medicare and Medicaid programs.

Among those charged is Alan MacKenzie, president of Takeda Pharmaceuticals of North America in Lincolnshire, a unit of Japan's Takeda Chemical Industries. TAP is a joint venture of Takeda Chemical and Abbott Laboratories of North Chicago.

A Boston-based health maintenance organization and a former TAP vice president who filed separate whistleblower suits against TAP will share $95 million as part of the settlement, according to federal officials.

More broadly, prosecutors said the settlement will send a "chilling" message to the U.S. drug industry to cease manipulating prices charged to the government and offering physicians gifts in exchange for prescribing drugs.

"This settlement will have a deep impact on the business practices of the pharmaceutical industry," said U.S. Atty. Michael Sullivan, whose Boston office handled the 4 1/2-year-old investigation.

"The urologists and the TAP employees who knowingly participated in this broad conspiracy took advantage of older Americans suffering from prostate cancer," Sullivan added.

The agreement will resolve criminal and civil charges brought by the government against the company. But prosecutors said more charges could be brought against individuals.

According to the indictment, TAP officials offered doctors enticements ranging from free drug samples to so-called "educational grants" that sometimes were used to pay country club bar tabs.

Successful sales representatives were rewarded with hefty bonuses, cash prizes and trips, according to the indictment. The top performers allegedly were feted at lavish junkets that cost TAP as much as $4 million a year, prosecutors said.

Despite the enormous penalty for TAP and a promise by the company to begin reporting lower, more accurate prices, it was not immediately clear if the settlement would translate into lower costs to the government, insurers or consumers.

Lupron is one of relatively few outpatient drugs covered by Medicare, the federal health insurer of the elderly. But under rules governing Medicare, legislation might be needed to give insurers and consumers the benefit of lower prices, according to federal officials and drug industry experts.

Company disputes allegations

TAP President Thomas Watkins said the company disputed many of the government's allegations but agreed to resolve the case to avoid being banned from the government insurance programs.

Watkins, who joined the company in 1998, said TAP admitted it provided free samples for physicians to bill health insurers, a violation of federal law. "The billing for free samples is wrong, and it should never have happened," Watkins said.

Details of TAP's price manipulation revealed in Wednesday's indictments confirm accounts in a May 1999 Tribune report about the drugmaker's bold marketing practices.

Lupron's staggering market success, with $800 million in annual sales, is dependent on the drug's coverage under Medicare. According to the indictment, TAP boosted its sales by cutting the prices it charged doctors for the drug while inflating the prices used by Medicare to reimburse providers, thus widening the profit margin for physicians.

The wrongdoing came to light in a 1996 whistleblower suit filed by former TAP vice president of sales Douglas Durand, who left the company after concerns about "illegal marketing conduct of some of its employees."

Neither Durand, who is slated to receive $77 million, nor his attorney could be reached for comment.

About a year later, Dr. Joseph Gerstein, a medical director at Tufts Associated HMO outside Boston, alleged in a suit that he was offered bribes by TAP executives to switch prostate cancer patients to Lupron from a less-expensive competitor.Gerstein turned down the offer and notified federal authorities. He and Tufts then filed a whistleblower suit. He was unavailable for comment.

Gerstein will receive a small portion of the $17 million awarded to Tufts. The non-profit HMO will spend the remainder on charitable projects, according to his attorney.

Under the federal False Claims Act, individuals filing suits that uncover wrongdoing can share from 15 percent to 25 percent of the civil damages recovered.

Fighting the charges

MacKenzie, 40, of Barrington, who was vice president of sales at TAP before joining Takeda Pharmaceuticals, will fight the charges, said his attorney, David Stetler of Chicago.

"Alan is a decent and ethical man who tries to do things the right way, and I am confident we can establish that at trial," Stetler said.

Others charged are: Janice Swirski McCourt, 40, of Chestnut Hill, Mass.; Henry Van Mourick, 43, of Roseville, Calif.; Donna Tom, 37, of New York; Kimberlee Chase, 35, of Dover, Mass.; David Guido, 30, of Colchester, Conn.; and Dr. John Romano, 48, of Plymouth, Mass.

Van Mourick and Guido are listed in the indictments as current TAP employees.

Guido's attorney, Jeremy Margolis of Chicago, said his client "has done nothing wrong" and will be fully vindicated.

McCourt and Chase declined to comment. Van Mourick, Tom and Romano could not be reached.

Of the $875 million total penalty, $290 million is in the form of a criminal fine--the largest ever in a health-care fraud case, prosecutors said. TAP also agreed to pay $559.5 million in civil penalties to the federal government and $25.5 million to state Medicaid programs.

Both Abbott and Takeda said this year that they had set aside adequate funds to pay their shares of the penalties. There were no allegations of wrongdoing against either firm.

Under the settlement agreement, TAP will be required to report actual sales prices to the Centers for Medicare & Medicaid Services. But the agency will continue to use a different pricing benchmark--known as average wholesale price, or AWP--to determine reimbursement to doctors.

"The law would have to be changed to affect Medicare reimbursement," said Zachary Bentley, whose Key West, Fla.-based pharmacy has filed whistleblower suits against other drugmakers

Lupron's sales price to doctors is about 40 percent below its AWP, which is set by TAP, Bentley said.